REMARKS/ARGUMENTS

Claims 1 and 3-9 are pending in the present application. Claims 1 and 3 are amended to clarify their description of applicants' external medicine. The amendment is supported by the application as filed and thus no new matter is introduced.

Furthermore, new claims 10-13 are proposed herein for addition to the application. Claims 10 and 12, which exclude an oil component from the claimed external medicine, are believed to be fully supported by the teaching(s) set forth at, e.g., p. 2, lines 6-13 of applicants' specification. The inventors state therein that, although adrenocortical steroid is known to have a significant medicinal value, the material fails to produce a good effect when it is included in a composition that contains oil for the medical treatment of atopic dermatitis and the like. The specification then goes on to state that the inventors believe that at least one reason why the effect of the adrenocortical steroid is not as good as may be expected is due to, "the oil contained in the ointment or the oil used for providing the shape of [the] cream, ... [since] the oil contained dissolves the horny layer of the skin and prevents reproduction of the healthy skin.". Further to the above, as noted below in the discussion of new claims 11 and 13, the external medicine which is the subject of the present application is referred to throughout the application as being an aqueous solution, i.e., in the written description, as well as in the Examples provided to illustrate various compositions according to the invention. Applicants submit, therefore, that the disclosure of the application as originally filed thus clearly directs one having an ordinary level of skill in this art to avoid the presence of oil in the claimed external medicine in order to avoid the deficiencies discussed on specification page 2.

Support for proposed new claims 11 and 13, wherein the medicine is described as being in the form of an aqueous solution, is found throughout applicants' specification. See, for example, p. 3, lines 2-3, 8 and 10 under the heading "Disclosure of Invention". See also line 2 on p. 4 under the heading "Best Mode for Carrying Out The Invention". Also see the Examples at pp. 6 and 9-12.

No new matter is, therefore, believed to included in proposed new claims 10-13 and their entry into the file of the present application is respectfully requested. Upon such entry, claims 1 and 3-13, as amended, will be pending in the application.

Rejection Under 35 U.S.C. §112

Claims 1, 3 and 4 are rejected under 35 U.S.C. 112 second paragraph, for the reasons set forth at p. 1 of the Detailed Action. In response, claims 1 and 3 are amended in a manner that is believed to overcome the subject rejection. The Examiner is respectfully requested to reconsider and withdraw the rejection.

Rejection Under 35 U.S.C. §103

Claims 1 and 3 to 9 are rejected under U.S.C. 103(a) as being allegedly unpatentable over Yamada (EP 0780129) in view of Griesbach (USP No.6875754), JP 240 (JP-A-No. 10-25240), Schmidt (USP No. 5578300), Kludas (USP No. 5547997) and Yvin (5980916) as evidenced by Kludas (EP 0668072). The rejection is respectfully traversed.

Applicants' claims are directed to an external medicine and treatment method for treating atopic dermatitis and psoriasis vulgaris, by which improved effects can be achieved without producing negative side effects, in contrast to other compositions known and used in the prior art for this purpose. For the reasons provided below, applicants respectfully submit that their claimed composition and method are believed to be distinguishable from the combined disclosure of the references cited to reject their claims and, further, that the beneficial results obtained with the use of these composition and method provide additional support for the novelty and non-obviousness thereof.

Among the cited references, it appears that only Yamada, JP 240 and Griesbach disclose the treatment of psoriasis vulgaris. In the case of Yamada in particular, as applicants have previously demonstrated in their prior responses filed in this application, the treatment of psoriasis vulgaris is less effective than the results achieved with applicants' claimed composition and method.

As regards the Griesbach reference, as applicants also argued in the response to the prior Office Action, various glucans such as krestin (see, e.g., No. 1 and Nos. V1 to V7 in Table 2 of Griesbach) are used in Comparative Examples, wherein skin aging tests are conducted, wherein it was determined that the oil in water (O/W) skin creams of Examples V1 to V7 have lower activity than the activity of applicants' composition as demonstrated in Example 1 of the present application.

Furthermore, there is no specific disclosure in Griesbach that krestin is effective for treating, in particular, as claimed, psoriasis vulgaris, although Griesbach does recite in claim 3

that a method of treating skin conditions or skin diseases, i.e., psoriasis. Furthermore, as argued in the response to the prior Office Action, Griesbach discloses a method of treating skin conditions or skin diseases comprising a step of applying to the skin a solution including water soluble β-(1,3) glucans, which have intact β-(1,3) side chains and are free from repetitive β-(1,6) linkages, as active substances. The disclosure contained in Griesbach favoring a compound which does not have β-(1,6) linkages thus is believed to teach away from applicants' claimed compositions and methods since xyloglucan and laminaran disclosed in claims 1 and 5 have β-1,6 linkage.

In the Office Action it is, however, argued that, "Griesbach has been cited for krestin and not xyloglucan or laminarin, which is taught by other references that are newly cited in this action." . However, even though Griesbach has been cited for its disclosure regarding krestin and new references disclosing xyloglucan or laminarin are cited, applicants respectfully reiterate their contention that Griesbach discloses a method of treating skin conditions or skin diseases comprising a step of applying to the skin a solution including water soluble β-(1,3) glucans, which have intact β-(1,3) side chains and are free from repetitive β-(1,6) linkages, as active substances. Such a disclosure regarding a compound which does not have β-(1,6) linkages thus, as noted above, teaches away from the composition and method recited in claims 1 and 5 of the present application, since xyloglucan and laminaran, which have β-1,6 linkage, are recited as being present in combination with krestin in the subject claims as essential components.

In light of the points raised above, therefore, applicants submit that there would be no sufficient reason for a person having ordinary skill in the art to combine Griesbach, which discloses that xyloglucan and laminaran are undesirable, with the other, i.e., newly cited references, which teach that that xyloglucan and laminaran are preferably used.

Furthermore, the Office Action states that, "Examiner maintains that even with 1-6 linkages, the beta glucans show significant activity (refer to a treatment of skin aging test of Griesbach)." However, there is no Comparative Example wherein no glucan is included in a cream. Furthermore, the O/W skin creams shown in Table 1 of Griesbach (Examples 1 and V1 to V7) include glycerol, oils and the like, as well as glucan (please refer to Table 1 of Griesbach), and a blank test, i.e., without glucan, has not been conducted. Accordingly, applicants are of the view that Examples V1 to V7 shown in Table 2 fail to show that all beta glucans shown in Table 2 have significant activity, although the Office Action argues that this is so.

In addition, oils and the like are used in a method of treating skin conditions or skin diseases disclosed in Griesbach. In the presently claimed composition and method, the use of oils is undesirable for the reasons noted, e.g., at p. 2, lines 6-13 of the present specification. As stated therein, when oil is used for the medical treatment of atopic dermatitis and the like, the desirable beneficial effects tend not to be obtained due to the oil contained in the ointment or cream, since the oil may dissolve the horny layer of the skin and prevents reproduction of the healthy skin.

Still further, among the cited references, it seems that only JP 240 discloses a composition that is effective for treating atopic dermatitis. That is, the other cited references do not disclose an effect of treating atopic dermatitis. JP 240, moreover, also discloses treating psoriasis. The Office Action argues that there is a recitation in JP240 that ribose, arabinose and trehalose may be used in an amount of from 1 to 100%. However, as applicants noted in their response to the previous Office Action issued in this case, JP 240 discloses a bath powder, which is entirely unlike an external medicine for treating dermatitis of the present invention of the present invention. That is, a bath powder is not an external medicine and is not applied directly onto an individual's skin. Bath powder is dissolved in hot water when the powder is used. Accordingly, the skin of a subject contacts a hot water wherein trehalose is dissolved in an amount of about 0.00025 % by weight. In this regard the Examiner is respectfully referred to Example 1 of JP 240 wherein 50 g of a bath powder is dissolved in 200 L of hot water. The disclosure of the use of such an amount of the material by JP 240 thus fails to disclose 0.5 to 55% by weight of trehalose as is recited in applicants' claims.

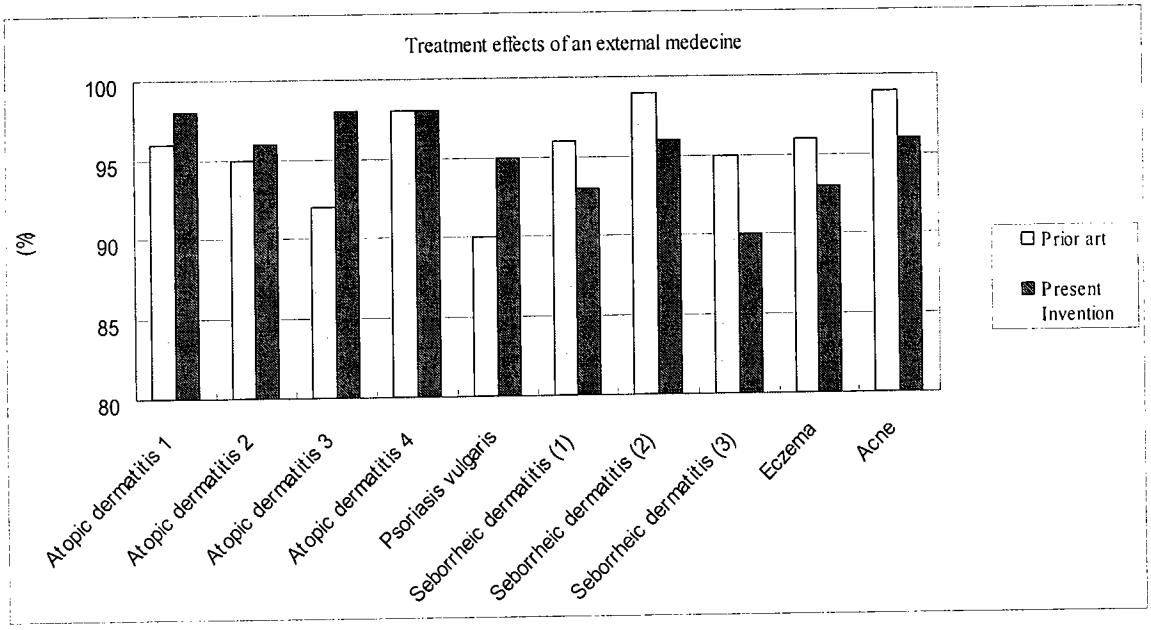
With regard to the Schmidt reference, applicants note that the patent discloses a method of treating allergic contact dermatitis, wherein a polymeric material including gelatin and pectin, which generates a hydrogen peroxide, is used to induce an oxidative stress and obtain a heat shock response. The use of pectin in Schmidt is different from how it is used in the composition and method recited in claims 1 and 5 of the present application. Furthermore, applicants submit that the allergic contact dermatitis disclosed in Schmidt is different from atopic dermatitis and psoriasis vulgaris as is recited in the present claims, and that a person with ordinary skill in the art would not combine Schmidt with the other cited references in order to treat atopic dermatitis and psoriasis vulgaris. Schmidt fails to disclose any effect of the compositions described therein upon such atopic dermatitis and psoriasis vulgaris.

Turning next to Kludas (USP No. 5,547,997) and Kludas (EP 0668072), Kludas discloses the use of pectin and xyloglucan. However, oils are used in the cosmetic composition and method of treating skin disclosed in Kludas. In the case of the presently claimed composition and method, it is not preferable to use oils for the reasons already discussed above (see, e.g., p. 2 of applicants' specification). Furthermore, it seems that the amounts recited in applicants' claims (0.5 to 55% by weight) of pectin and xyloglucan also are not disclosed. Furthermore, Kludas (USP No. 5,547,997) and Kludas (EP 0668072) also fail to disclose any therapeutic effect of the compositions described therein on, specifically, atopic dermatitis or psoriasis vulgaris.

Regarding Yvin (5,980,916), the subject reference discloses use of laminaran. However, oils are used in cosmetics and a skin treatment drug disclosed in Yvin. In the presently claimed compositions and methods, as indicated above it is not preferable to use oils. Furthermore, Yvin also fails to disclose any beneficial effect for the compositions disclosed therein upon atopic dermatitis and psoriasis vulgaris.

As pointed out above, applicants' claims are directed to an external medicine and a treatment method for treating atopic dermatitis and psoriasis vulgaris. With the use of the claimed composition and method, it is possible to treat atopic dermatitis and psoriasis vulgaris, such that the skin may be repaired while the skin is also protected, without damaging any of the skin proteins. Furthermore, the particular combination (i.e., in terms of components and amounts) which constitutes the composition presently claimed by the inventors renders it possible to prepare the external medicine of the present invention without including any oils. The external medicine of the present invention is thus in the form of an aqueous solution. This, therefore, permits one to use the claimed composition and method in the treatment of atopic dermatitis and psoriasis vulgaris without producing negative side effects such as those attributable to the presence of oil(s) in certain compositions known in the prior art.

The following bar graph demonstrates the beneficial effects attainable in the treatment of atopic dermatitis and psoriasis vulgaris with the use of an external medicine as claimed herein. The graph was prepared by the applicants based on the results provided in the Examples provided in the specification of the present application. As compared with the closest prior art, that is, as compared with external medicine disclosed in the Yamada reference, excellent effects of the present invention are shown regarding atopic dermatitis and psoriasis vulgaris.



In summary, therefore, among the seven references that are combined to reject applicants' claims, four of said references, i.e., Griesbach (USP No.6875754), Kludas (USP No. 5547997), Yvin (5980916) and Kludas (EP 0668072)) disclose the use of oils. As indicated above, the presence of such oils is avoided, i.e., due to their negative effects as described, for example, at p. 2 of the present specification. Applicants' respectfully submit that, in their view as ones having an ordinary level of skill in the relevant art, a person with such ordinary skill would not find it suggested to combine the four references wherein oils are used, with the formulation described by Yamada (EP 0780129).

Furthermore, as indicated above Griesbach (which is cited for its disclosure regarding krestin) includes disclosure which teaches away from the compositions and methods of the present application.

Still further, JP 240 discloses a bath powder, such that what the skin of a subject actually contacts is hot water including trehalose in an amount of about 0.00025 % by weight. Furthermore, in the cited reference, there is no reference wherein trehalose is included in an amount of 0.5 to 55% by weight.

Schmidt discloses a method of treating allergic contact dermatitis unlike the present invention, and the use of pectin in Schmidt is different from the use of pectin as recited in claims 1 and 5 of the present application.

Kludas discloses a cosmetic composition wherein pectin, xyloglucan and oils are included, as well as a method of treatment of skin. The presently claimed amounts (0.5 to 55% by weight) of pectin and xyloglucan are not disclosed in Kludas.

Yvin discloses cosmetics and a skin treatment drug wherein laminaran and oils are used.

Furthermore, even if one with ordinary skill in the art were to combine xyloglucan, trehalose, krestin, laminaran and pectin cited in the six references besides Yamada, with an external medicine prepared according to the teachings of Yamada, such individual would not definitively know what type of dermatitis would be treatable by the resultant composition. In this regard, reference is made to the above graph wherein different effects are shown in the case of different types of dermatitis.

Applicants thus respectfully submit that the compositions and methods recited in claims 1 and 5 of the present application are not taught or suggested by the seven references combined to reject applicants' claims, whether taken alone or in combination. As the Examiner is aware, hindsight is to be avoided during the examination of the application and a legal conclusion regarding the novelty and non-obviousness of applicants' claims should, therefore, be reached only on the teachings actually set forth in the prior art.

Claims 1 and 5 are believed by applicants to be both novel and not obvious. Moreover, the claims depending from these independent claims are also believed to be allowable since they each contain all of the features set forth in their 'parent' independent claim. The Examiner is, therefore, respectfully requested to reconsider all of the grounds for rejection of applicants' claims and to issue a Notice of Allowance for all of the claims set forth above.

Respectfully submitted,

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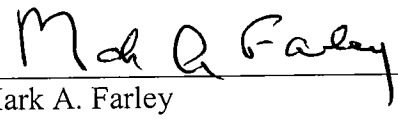

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